

AF 1723/\$

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Herbert Mann

Serial No.: 10/016,231

Filed November 2, 2001

Group Art Unit: 1723

For: CHROMATOGRAPHY COLUMN
AND METHOD OF OPERATION

Examiner: E. Therkorn

BRIEF ON APPEAL

Commissioner of Patents and Trademarks
Arlington, Virginia 22313-1450

Sir:

Further to the Notice of Appeal filed September 29, 2003, herewith are three copies of Appellants' Brief on Appeal. The statutory fee of \$160 for the Notice of Appeal fee has been paid and enclosed is \$160 for the submission of the appeal brief. Please charge any additional fee or credit any overpayment to Deposit Account No. 13-3403. Three copies of this page are attached for this purpose.

I. PRESENTATION OF THE APPEAL

A. Real Party in Interest

The real party in interest is Appellants' assignee, Mann Welding Company, a Tennessee corporation with its principal place of business at 1400 Hamill Road, P.O. Box 71965, Chattanooga, Tennessee 37407.

11/24/2003 JBALINAN 00000110 133403 10016231

01 FC:2402 5.00 DA 160.00 OP

B. Related Appeals and Interferences

There are no related appeals and interferences.

C. Status of Claims

At the time of the final Office Action, claims 1-11 were pending in the application. However, the application was initially filed with 20 claims. Claims 1-11 were directed to a method, and claims 12-20 were directed to an apparatus. The Applicant elected the method claims 1-11 with traverse and was unsuccessful in convincing the Examiner to examine the apparatus claims during prosecution. Applicant appeals the final rejection of claims 1-11 and also appeals the election requirement which removed claims 12-20 from consideration.

A copy of the claims subject to this appeal appears in Appendix A.

D. Status of Amendments

No proposed amendments have been proposed or entered after final.

E. Summary of Invention

Most generally, the present invention is directed to an apparatus and method of operating a chromatography column for performing maintenance, such as changing retention screens within the chromatography column without requiring the use of a crane to disassemble the column. (Page 1, lines 4-7). Chromatography columns typically require periodic maintenance and inspection within the column. (Page 2, lines 16-17). Such maintenance can include the replacement of resin retention screens. (Page 3, lines 1-2). The resin retention screens are typically held to a plunger with connectors and an inner clamp nut. (Column 3, lines 3-4). In the prior art, the plunger had to be completely

removed from the cylinder with a crane in order to replace the screen and/or work on the distributor plate since the plunger could only be lifted about two inches or less above the cylinder which did not provide enough clearance for a mechanic to access the connectors or inner clamp nut to disconnect and replace the screen. (Page 3, lines 4-8).

A chromatography column 10 of the preferred embodiment comprises an elongated hollow cylindrical housing 12, or cylinder, having a dispersion section 14 at the top and a collection section 16 at the bottom. (Page 7, lines 1-3). The dispersion section 14 includes a cylinder drum 18 having an upper cylindrical plunger head 20 at the lower end. (Page 7, lines 3-4). The plunger is normally disposed within the upper portion of the housing 12 such as is illustrated in the first operational position in Figure 1. (Page 7, lines 4-6). The plunger 29 may also be moved, such as that the drive system, similar to the hydraulic arrangement illustrated to the second operational position of Figure 2 (Page 7, lines 6-8). The movement of the head 20 allows for the compression of media to “pack” resin and/or for the use of particularly sized media column within the cavity changing formed between the dispersion and collections sections 14,16 and/or between the plunger 20 and the base 64. (Page 7, lines 8-11). The dispersion section 14 may also include a product inlet 24 along with an inlet manifold 26 to treat incoming fluid throughout a top portion of a resin column contained within the cavity 22. (Page 7, lines 12-14) An inlet screen 20 may be connected to the plunger head 20 by connectors and/or the inner clamp nut 30 (Page 7, lines 14-16). The distributor plate 31 may be removable as well. (Page 7, line 16).

In order to remove the plunger 20 in an operational mode from the first operational position in Figure 1 to the second operational position in Figure 2, a drive

system, illustrated as a hydraulic system is preferably utilized. (Page 8, lines 3-5). The drive system is comprised of at least one, and preferably three or more drive cylinders 34 which move pistons 36 coupled to drums 18 (Page 8, lines 7-9). A portion of the drive pistons is a threaded portion 38 which allows for the drive piston 36 to connect or couple to connection arms 40 at specific locations relative to the drive piston 36 with nuts 42,44. (Page 8, lines 9-11). The drive piston includes a control unit 48 which may be operating to control movement of the plunger 20. (Page 8, lines 14-15).

When intrusive maintenance is to be performed within the cavity of the cylinder 12 (which does not include visual inspection), the drive piston 48 has been constructed to assist in this aspect rather than needing a crane to lift components of the column 10 after substantial disassembly of the column 10. (Page 9, lines 2-5). Intrusive maintenance is defined herein as needing more than two inches clearance between the top of the cylinder and the bottom of the plunger. (Page 9, lines 5-7).

Figure 4 shows a first maintenance position of the plunger 20 wherein the plunger 20 is raised a predetermined distance from a top 54 of the cavity 22 within the cylinder. (Page 9, lines 8-10). The predetermined distance is greater than three inches, preferably greater than six inches, and most preferably about twelve inches (Page 9, lines 10-11). The predetermined distance is greater than the small distance allowed in the prior art designs which was intended for visual inspection of the interior of the column only (Page 9, lines 11-13). The predetermined distance may be accomplished through the use of a longer piston 36 than has been utilized in the prior art (Page 9, lines 13-14).

In order to perform a second maintenance operation, such as removal of the lower screen 60 which is typically positioned so that its outer edge 62 is between the cylinder

12 and the collecting section 16, the cylinder 12 may be raised by the drive system as illustrated in Figure 5 (Page 10, lines 6-9). The bolts 58 which normally secure the cylinder to the base 64 are removed, and the nut 42,44 may be coupled to the piston 36 to drive the cylinder 12 along with the drum 18 upwardly as illustrated (Page 10, lines 9-11). The collection section 16 may be substantially similar to the dispensing section 14 as illustrated, or it may be different in other embodiments (Page 10, lines 11-13). A controller 66 may be provided to control positions of the slurry fill valve 32 and the slurry outlet valve 68 (Page 10, lines 13-14).

Safety rods 69 may be inserted along portions of rim 70 illustrated in Figure 3 to support the weight of the drum 18 and/or cylinder 12 during the maintenance operations so that hydraulic failure will not result in dropping of either of the plunger 20 and/or the cylinder 12 (Page 10, lines 15-18). A safety rod could be similar to the guide rods 46 with retaining lips, possibly formed by nuts on threaded portions at the rims or lips 70,72,74 of the cylinder 12, base 64 and support arm 40 or may be separate members as illustrated (Page 10, line 19—Page 11, line 1). At least one guide rod 46, safety rod 69 and/or drive piston 36 may be removed to assist in installing support rods and/or removing screens 28,60 (Page 11, lines 1-3).

F. Issues

1. Whether the Examiner properly rejected claims 1-11 as being obvious over the combination of “that which is considered to be owned in the prior art on Page 1-4 of the specification” and Hatch, U.S. Patent No. 5,667,675.
2. Whether the Examiner was correct in forcing election between the method claims (claims 1-7) and the apparatus claims (claims 12-20).

I. Claims

1. Claims 1-6 and 8-11 stand or fall together and they should be considered together. Claim 7 has at least one separate basis for allowability.
2. Claims 12-20 stand and fall together and they should be considered together.

II. Argument

A. Obviousness Rejection of Claims 1-11 Based on Hatch, U.S. Patent No. 5,667,675 in view of “that which is conceded to be old in the prior art on Pages 1-4 in the instant specification.”

According to the Office Action: “At best, the claims differ from what is conceded to be old prior art on Pages 1-4 of the instant specification in the clarity of raising the plunger high enough to perform maintenance.” The Examiner cites Hatch (U.S. Patent No. 5,667,675) (Column 6, lines 8-12 and Column 10, lines 23-40) for the proposition that “it is desirable to raise the plunger to provide access to the column.”

Column 6, lines 8-12 of Hatch states:

the column tube, the compression rod and compression piston being depicted in a raised position with the upper end of the column tube open to receive a slurry of the packing material for packing upon a downward movement of the compression piston into the column tube.

Column 10, lines 33-40 of Hatch is also provided below:

is removed from the column tube 35 and coupler 78 and the compression rod and piston are allowed to move upwardly out of the upward end of the column tube to the position shown in FIG. 6. The upper open end of the column tube 35 is then clear to allow a pouring of a slurry of packing material into the column tube for compression by the

compression piston 26 after an upper bed support is inserted into the column tube.

Column 6, lines 8-12 only discuss the provision of providing slurry into the column. This is certainly does not require the spacing of “intrusive maintenance” as defined in the specification of the present application. Specifically, intrusive maintenance has been consistently defined as follows: “Intrusive maintenance is defined herein as needing more than two inches clearance between the top of the cylinder and the bottom of the plunger.” (Page 9, lines 5-7). In Column 10, lines 32-40, once again, Hatch discusses the “pouring of a slurry of packing material” into the column tube for compression by the compression piston 26.

What has been totally ignored by the Office Action is the fact that the Hatch reference titled a “Collapsible Apparatus For Compressing Packing Material in Liquid Chromatography Columns and Methods of Use” teaches that after the column is utilized to compact slurry into a stationary phase, “the column is then ready for operation and **may be connected to a liquid chromatographic system for use.**” (Column 3, lines 60-62). (Emphasis added). When this is read in combination with Column 4, lines 1-12, it can be understood that the device shown described in the Hatch ‘675 Patent, acts as a compression apparatus and is not intended to provide an ability to run fluid through the column. The column must then be connected to a dispersion section and a collection section and only then can be provided with product processing.

In the prior art discussed on Pages 1-4 of the specification, the Applicant discloses that maintenance was performed on prior art chromatography columns. However, the Applicant disclosed that the plunger could not be raised high enough to perform **intrusive** maintenance. Intrusive maintenance has been defined in the specification and

above. In this prior art section of this patent application, the Applicant discusses the need for the use of a crane to lift prior art plungers to access internal components of the column.

The Office Action states: “the remarks urge patentability based upon the use of a dispersion section.” The Office Action misses the point. In claim 1, as amended on June 11, 2003, the Applicant requires an ability to provide a chromatography column having a dispersion section and a collection section opposing the dispersion section with a plunger connected to the dispersion section so that the dispersion section and plunger can be raised to a first maintenance position so that intrusive maintenance can be performed within a column. The plunger and the dispersion section is then lowered within the cylinder and then product is introduced into the cylinder through the dispersion section. While it is true that the Applicant has included the dispersion section, patentability is not urged solely based upon a dispersion section in the June 11, 2003, remarks. The ability to perform maintenance and provide product through the column was a distinguishing feature argued in that response.

By developing the hydraulic drive system for the apparatus disclosed, the Applicant provides a novel ability to accomplish the claimed method. It is only with hindsight and the use of the Applicant’s disclosure that the Examiner can formulate the obviousness rejection. The teaching or suggestion to make the claimed combination must be found in the prior art, not in the Applicant’s disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). Specifically, there is no mention or suggestion in the Hatch reference for an ability to perform intrusive maintenance on internal components of a functional chromatography column, (i.e., one in which product can be processed

through the column without a need to hook up additional components). Furthermore, there is no teaching for such crane-less capability in the prior art section in page 1-4 of the specification as originally filed. Accordingly, the prior art fails to provide objective evidence or objective evidence with a respect to a combination of these references to produce the claimed inventions. See In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ 2d 1313, 1317 (Fed. Cir. 2000). See also In re Fine, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988).

In Hatch, the plunger is raised to provide an ability to swap out packed column tubes in a compactor apparatus. (See Hatch, Column 4, lines 1-12). There is no teaching through the combination of Hatch and prior art chromatography columns discussed in the prior art on pages 1-4 of the specification for the ability to provide a functional chromatography column (i.e., one in which has a dispersion of collection section capable of processing fluid through a chromatography column). In fact, step (e) as claimed requires the capability of processing product in the column.

The logic the Office Action utilizes to form the obviousness rejection is flawed in that while dispersion sections are known in the prior art, there is no teaching or suggestion that the prior art could be modified to perform the claimed method of claims 1-6 and 9-11 without utilizing hindsight and use of the Applicant's disclosure.

It is important to remember that the mere fact that references can be combined does not render the resultant combination obviousness unless the prior art also suggests the desirability combination. In re Mills, 916 F.2d 680 16 USPQ 2d 1430 (Fed. Cir. 1990). Furthermore, it is important to remember that the fact that the claimed inventions is within the capability of one skilled in the art is not sufficient by itself to establish

prima facie obviousness. See *Ex parte Levengood*, 28 USPQ 2d 1300 (Bd. of Pat. App. & Inter. 1993).

However, it is even more noteworthy that the proposed modification cannot render the prior art unsatisfactory for its intended use. If the plunger structure shown in Hatch were placed on top of the prior art chromatography column, the plunger itself would prohibit the ability to provide liquid through the column and therefore prevent the implementation of the claimed method. Accordingly, since the proposed modification would render the prior art invention unsatisfactory for its intended purpose, there is no suggestion or motivation to provide the proposed invention. See *In Re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1994). Accordingly, a *prima facie* case of obviousness has not been established.

Claim 7 is allowable for the reasons stated above. Claim 7 is further allowable over the cited prior art in that it requires the additional step of engaging a safety mechanism after raising the plunger and disengaging the safety mechanism before lowering the plunger. The Examiner has not addressed this capability in any of the Office Actions. Accordingly, since all of the required elements and steps must be provided, this claim is allowable as a result of the failure of any of the cited prior art to provide such a teaching or suggestion.

B. Election Requirement. On January 2, 2003, the Examiner provided a restriction requirement requiring the Applicant to select between claims 1-11, drawn to a method of accessing into a chromatography column, and claims 12-20 drawn to a chromatography column apparatus. The Examiner proposed that the inventions were distinct. Specifically, the Examiner stated “the apparatus as claimed could be used to

perform another and materially different process. For example, the apparatus as claimed could be used as a chemical or biological reactor in a chemical or biological reaction process.”

On February 11, 2003, the Applicant responded by electing claims 1-11 with traverse. The Applicant quoted from MPEP § 805.05(h) which states that “if the applicant can provide a convincing argument to the alternative use suggested by the Examiner cannot be accomplished, the burden reverts back to the Examiner’s support of reliable alternative use or withdraw the requirement.” The applicant pointed out to the Examiner that the Examiner’s logic proposing that “the apparatus could be used as a chemical biological art in a chemical reaction processing” was flawed. The applicant observed that “the claimed method could also be utilized for the Examiner’s proposed process which such an apparatus.” This provided a showing that the method and apparatus were regarded the same invention. Under MPEP § 806.05(h) the burden should have shifted back to the Examiner.

However, the Examiner made no response to this election with traverse in Paper No. 4 of the Office Action dated March 11, 2003. The Examiner merely checked box 4a on Form PTOL 326 stating claims 12-20 were withdrawn from consideration without addressing the response made by the Applicant.

Section 806.05(h) of the MPEP specifically states “if the Applicant either proves or provides a convincing argument that the alternative suggested by the Examiner cannot be accomplished, the burden is on the Examiner to provide an alternative use or withdraw the requirement.” In formulating this election requirement, the Examiner not only failed to provide a viable alternative use, but failed to respond to the applicant’s argument.

Accordingly, the Examiner's examination of claims 12-20 should be properly conducted in the prosecution of this application without the need for requiring a divisional application.

Respectfully submitted,

MILLER & MARTIN




Stephen J. Stark
Reg. No. 43,152
Attorney for Applicants
832 Georgia Ave., Suite 1000
Chattanooga, TN 37402-2289
(423) 785-8229

CERTIFICATE OF MAILING

I hereby certify that the preceding Brief on Appeal is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

On this 17th day of November, 2003.


Beverly L. Middleton

APPENDIX A

1. A method of accessing the interior of a chromatography column comprising the steps of:
 - a) providing a chromatography column having a dispersion section connected to a product inlet and a cylinder with a plunger connected to a drive system, said plunger moveable within a cavity of the cylinder in an operational mode, and a collecting section opposing the dispersion section;
 - b) raising the plunger and dispersion section with the drive system a predetermined distance above a top of the cavity to a first maintenance position;
 - c) performing intrusive maintenance within the column without removing the plunger from the column;
 - d) lowering the plunger and dispersion section to an operational position within the cylinder with the drive system; and then
 - e) introducing product from the product inlet into the cylinder through the dispersion section with the plunger remaining in the cylinder.
2. The method of claim 1 wherein the step of the intrusive maintenance performed further comprises replacement of a screen connected to the plunger by at least a nut.
3. The method of claim 2 wherein the step of the replacement of the screen further comprises removing the nut located substantially at the center of the plunger.
4. The method of claim 2 wherein the step of replacement of the screen further

comprises removing the distributor plate.

5. The method of claim 1 wherein the step of raising the plunger a predetermined distance further comprises raising the plunger at least six inches.

6. The method of claim 5 wherein the step of raising the plunger a predetermined distance further comprises raising the plunger about one foot.

7. The method of claim 1 further comprising the step of engaging a safety mechanism after raising the plunger, and disengaging the safety mechanism before lowering the plunger.

8. A method of accessing the interior of a chromatography column comprising the steps of:

- a) providing a chromatography column having a dispersion section with a product inlet, a cylinder connected to base in an operational mode, and a drive system;
 - b) disconnecting the cylinder from the base;
 - c) raising the cylinder a predetermined distance above the base with the drive system to a first maintenance position;
 - d) performing maintenance within the column; and
 - e) lowering the plunger to the operational mode with the drive system
- returning the cylinder to the base;
- f) reconnecting the cylinder to the base; and then

g) introducing liquid product through the product inlet into the cylinder with the plunger in the operational mode.

9. The method of claim 8 wherein the drive system is connected to a plunger in the operational and further comprising the step of raising the plunger with the cylinder during the step of raising the cylinder the predetermined distance.

10. The method of claim 8 wherein the step of performing maintenance further comprises removing a screen.

11. The method of claim 10 wherein the step of providing a chromatography column further comprises locating the screen at least partially between the cylinder and the base in the operational mode.

12. A chromatography column comprising:

a drive system coupled to a plunger in an operational mode; and

a cylinder connected to a base, said plunger adapted to move within the cylinder in the operational mode; and

said drive system moves the cylinder a predetermined distance above the base for a first maintenance procedure.

13. The chromatography column of claim 12 wherein the drive system moves the plunger at least six inches above the top of the cylinder for a second maintenance procedure.

14. The chromatography column of claim 12 further comprising safety rods located between the cylinder and the base during the first maintenance procedure.
15. The chromatography column of claim 12 wherein the first predetermined distance is at least six inches.
16. The chromatography column of claim 15 wherein the first predetermined distance is at least one foot.
17. The chromatography column of claim 12 wherein the drive system moves the plunger a second predetermined distance above a top of the cylinder for a second maintenance procedure.
18. The chromatography column of claim 17 wherein the second predetermined distance is at least six inches.
19. The chromatography column of claim 18 wherein the second predetermined distance is between about six and about twelve inches.
20. The chromatography column of claim 12 wherein the drive system further comprises hydraulically driven pistons coupled to the plunger.